

TABLE—FLAGGING CRITERIA—Continued

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
		General (systemic) toxicity NOEL less than 100 times the current existing ADI.	8
Reproduction study	83–4	Reproductive effects NOEL less than 100 times the current ADI	9
Subchronic feeding study	82–1	Cholinesterase inhibition NOEL less than 100 times the current existing ADI. or General (systemic) toxicity NOEL less than 1000 times the current existing ADI.	10 11

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant (or registrant in the case of information submitted under FIFRA sec. 3(c)(2)(B)) shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) “I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.”

(2) “I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes.]”

[53 FR 15992, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 158.35 Flexibility of the data requirements.

Several provisions of this part provide EPA flexibility in requiring (or not requiring) data and information for the purposes specified in § 158.20(b). These provisions are summarized in this section and discussed elsewhere in this part.

(a) The Agency encourages each applicant, particularly a person applying for registration for the first time, to consult with the Product Manager for his product to resolve questions relating to the protocols or the data requirements before undertaking extensive testing under § 158.40.

(b) Any applicant who believes that a data requirement is inapplicable to a specific pesticide product may request a waiver of a data requirement under § 158.45.

(c) The Agency may require an applicant to provide additional data or information beyond that specified in subparts C and D of this part when these data are not sufficient to permit EPA to evaluate the applicant’s product under § 158.75.

(d) Several policies are in effect that govern the data requirements for registration of products having minor uses. These policies reduce substantially the data requirements that need to be met on the basis of limited exposures and economic equity, and allow case-by-case decision making to determine the specific needs for each kind of use under § 158.60.

(e) The data requirements and guidelines are not static documents. Section 3(c)(2) of FIFRA states that the administrator “shall revise such guidelines from time to time.” Therefore, the data requirements and guidelines will be revised periodically to reflect new scientific knowledge, new trends in pesticide development, and new Agency policies under § 158.80.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.40 Consultation with the Agency.

This part establishes data requirements applicable to various general use patterns of pesticide products, but some unique or unanticipated aspect of a proposed product’s use pattern or composition may result in the need for